

COPY FOR IB
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 06 FEB 2004

WIPA SET

Applicant's or agent's file reference JL-18248-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/KR2002/002443	International filing date (day/month/year) 26 DECEMBER 2002 (26.12.2002)	Priority date (day/month/year) 27 DECEMBER 2001 (27.12.2001)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 9/107		
Applicant CJ CORPORATION et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 24 JUNE 2003 (24.06.2003)	Date of completion of this report 30 JANUARY 2004 (30.01.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer CHANG, Jin Ah Telephone No. 82-42-481-5602



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2002/002443

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages _____☐ the claims, Nos. _____☐ the drawings, sheet _____5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2002/002443

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims <u>1-7</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims <u>1-7</u>	YES
	Claims _____	NO
Industrial applicability (IA)	Claims <u>1-7</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)

The present invention claimed in claims 1-5 and 6-7 is related to a microemulsion preconcentrate comprising an active component, an oil, a surfactant and a hydrophilic solvent selected from the group consisting of propylene glycol diacetate, propylene glycol monostearate, and salts of the foregoing materials, and to an oral pharmaceutical preparation comprising said microemulsion preconcentrate.

1. Prior Art

The following documents identified in the International Search Report have been considered for the purpose of this report:

D1= US 6,159,933 (12 December 2000)

D2= WO 97/22358 A (26 June 1997)

D1 discloses pharmaceutical compositions in the form of an emulsion concentrate or microemulsion preconcentrate which comprise a cyclodextrin as an active ingredient; propylene carbonate as a hydrophilic solvent, glycerides as a lipophilic solvent, and a surfactant.

D2 discloses a microemulsion preconcentrate which comprises a cyclosporines as an active ingredient, tocopherol derivatives as a hydrophobic component, propylene carbonate as a hydrophilic component, and a surfactant.

2. Novelty

The cited documents only describe the general state of the prior art about a microemulsion preconcentrate and do not disclose anything about propylene glycol diacetate, propylene glycol monostearate, and salts of the foregoing materials as a hydrophilic solvent in the microemulsion preconcentrate. Therefore, the subject matter of claims 1-7 is novel over the prior art cited in the International Search Report and meets the criteria set out in PCT Article 33(2).

(Continued in the Supplemental Box.)

INTERNATIOAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2002/002443

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 does not meet the requirement of PCT Article 6 taken in combination with PCT Rule 6.3(b) that any dependant claim must contain all the technical features essential to the definition of the invention. The weight ratio of each component is essential to forming a microemulsion preconcentrate but there is no description about the weight ratio in claim 1. Therefore, claim 1 does not fully define the technical feature of the invention.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2002/002443

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V

3. Inventive Step

The purpose of the present invention is to provide a microemulsion concentrate, being applicable to hydrophilic drugs (e.g. gabapentin) or protein drugs (e.g. insulin) as well as hydrophobic drugs (e.g. cyclosporin) by using a hydrophilic solvent such as propylene glycol diacetate, propylene glycol monostearate, and salts thereof, and having low interaction with a gelatin shell during capsulation to thus secure the stability of the product.

Also, the present invention shows an unexpected effect about the stability and low reactivity with a gelatin soft capsule shell in Examples 9-11 (pp. 11-14). This is not considered to be obvious to a person skilled in the art. Therefore, the subject matter of claims 1-7 is considered to involve an inventive step under PCT Article 33(3).

4. Industrial Applicability

The subject matter of claims 1-7 is considered to be industrially applicable under PCT Article 33(4).